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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/660,203
Filing Date: September 11, 2003
Appellant(s): JOSEPH ET AL.

Christopher Goff
Registration No. 41,785
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 14, 2007 appealing from the Office action mailed April 18, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0120241	TYRELL et al	08-2002
5,869,075	KRZYSIK et al	02-1999
5,643,899	ELIAS et al	07-1997

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6,103,267	MITCHNICK et al	08-2000
WO 00/64409	KRZYSIK et al	11-2000
6,475,197	KRZYSIK et al	11-2002
2005/0101927	Wael et al	05-2005
2005/0058693	Wael et al	03-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(A) Claims 1-4, 8-10, 12-13, 15-16, 25-31, 34-35, 39-41, 43-45, 52-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Krzysik (5,869,075).

Krzysik discloses a composition comprising from about 30-90% of hydrophilic solvent, from about 10-50% of high molecular weight polyethylene glycol having a molecular weight of about 720 or greater; about 5-40% of a C14 to C30 fatty alcohol, said composition having a melting point from about 30-70C and a penetration hardness of from about 5 millimeters to 360 millimeters. See column 2, lines 1-10.

The amount of hydrophilic solvent is from about 30-90%. Suitable hydrophilic solvents include, but are not limited to, the following materials: water, propylene glycol, low molecular weight polyethylene glycols (molecular weights of less than 720 and liquid at room temperature), methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate, and silicone glycols.

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Additional ingredients include antiacne actives; antifoaming agents; antimicrobial actives; antifungal actives; antiseptic actives; antioxidants; astringents; colorants; deodorants; emollients; external, anesthetics, or antipruritics; film formers; humectants; natural moisturizing agents; skin conditioning agents; skin exfoliating agents (alpha hydroxy acids and beta hydroxyacids); skin protectants; solvents; sunscreens; and surfactants. See column 3, line 35 to column 4, line 10. These are added in an amount of 0.5-40%. See column 4, lines 25-30.

Further, the composition can contains 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters. See column 4, lines 10-25.

Example 7 comprises 10% propylene glycol (humectant); 10% PEG-400 (compatibilizing agent); 20% PEG-1000 and 30% PEG-8000 (immobilizing agents); 10% dimethicone copolyol (silicone emollient); and 20% hydrogenated starch hydrolysate.

Example 11 comprises 35% PPG (compatibilizing agent) ; 20% PEG-8000 (immobilizing agents); 10% cetyl alcohol ; 10% stearyl alcohol ; 10% hispagel (hydrogel humectant); 10% dimethicone (emollient); and 5% myristyl myristate (fatty ester oil -skin barrier agent). Note that the combination of the high molecular weight PEG and fatty alcohols read on the instant weight percent of the immobilizing agent. Further, the general disclosure discloses the use of high molecular weight PEG in an amount of 10-50%.

Example 12 comprises 28% PPG (compatibilizing agent); 15% PEG-8000 (immobilizing agents); 10% cetyl alcohol (immobilizing agents); 10% stearyl alcohol (immobilizing agents); 15% hydrogenated starch hydrolysate (humectant); 10% dimethicone (emollient); 7% lubrasil (dispersing agent) and 5% myristyl myristate. Note that the combination of the high

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molecular weight PEG and fatty alcohols read on the instant weight percent of the immobilizing agent. Further, the general disclosure discloses the use of high molecular weight PEG in an amount of 10-50%.

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

(B) Claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Tyrell et al (20020120241).

Tyrell et al disclose a composition comprising 28% propylene glycol (compatibilizing agent); 5% hydrogenated starch hydrolysate (humectant); 1% chitosan polymer; 25% of PEG 10,000 (immobilizing agents); 25% benzyl alcohol (immobilizing agents); 2% laureth-3 (dispersing agent); 3% laureth-4 (dispersing agent); 10% dimethicone (emollient); 1% sunflower oil; 0.8% soy sterol. See Table 1, **example 13**. Note that the combination of the high molecular weight PEG and benzyl alcohol read on the instant weight percent of the immobilizing agent.

Example 20 discloses a composition comprising 10% propylene glycol (humectant), 4% PEG-400 (compatibilizing agent); 5% chitosan polymer; 15% of PEG 10,000 (immobilizing agents); 10% benzyl alcohol (immobilizing agents); 10% emulsifying wax (dispersing agent); 20% dimethicone treated zinc oxide (emollient); 10% sunflower oil; 1% cholesterol. Note that

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the combination of the high molecular weight PEG and benzyl alcohol read on the instant weight percent of the immobilizing agent.

The composition has a penetration hardness of about 54 to 365 millimeters and a melting point of about 32 to 100 degrees C. See [0147].

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

(C) Claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/64409 to Krzysik et al.

Krzysik et al disclose a hydrophilic composition comprising from about 10-95% of a hydrophilic solvent, from about 5-95% of a high molecular weight polyethylene glycol (preferably having a molecular weight of about 720 or greater), from about 1-30% of a C14 to C30 or greater fatty alcohol, from about 0.5-30% of humectant, from about 1 to about 20% of an emulsifying surfactant having an HLB range greater than 7, from about 0.1-10% of sterol or sterol derivative, and from about 0.1-30% of natural fats or oils. The hydrophilic composition has a melting point from about 30 °C. to about 100 °C. The composition also has a penetration hardness of from about 5 millimeters to 360 millimeters. See page 3, lines 92-105.

More specifically the hydrophilic solvent may be in an amount of 25-75%, the high molecular weight PEG in an amount of 15-50%, the fatty alcohol in an amount of 1-30%, the

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surfactant in an amount of 1-20%, the sterol in an amount of 0.1-10%, and the natural fat or oil in an amount of 0.1-30%. See column 7, lines 220-235. Preferably the melting point of the composition is from 50-60 degrees C and has a penetration hardness of 5-100 millimeters. See page 15.

The hydrophilic component (compatibilizing agent) is selected from water, propylene glycol (PPG), low molecular weight polyethylene glycols, glycerin, and hydrogenated starch hydrolysate. See page 5, second paragraph.

The high molecular weight PEG (the immobilizing agent) may be PEG 1400, PEG 8000, PEG 10,000. See page 5, second paragraph.

The humectant may be glycerin, sorbitol, or hydrogenated starch. See page 5, second paragraph.

The surfactant may be glyceryl stearate, glycol stearate, or an emulsifying wax. See page 5, second paragraph.

The sterol may be soy sterol, cholesterol, or lanasterol. See page 5, second paragraph.

The natural fat or oil may be sunflower oil, borage oil, or avocado oil. See page 5, second paragraph.

The composition may comprise other additives such as antiacne actives; antifoaming agents; antimicrobial actives; antifungal actives; antiseptic actives; antioxidants; astringents; colorants; deodorants; emollients; external, anesthetics, or antipruritics; film formers; humectants; natural moisturizing agents; skin conditioning agents; skin exfoliating agents (alpha hydroxy acids and beta hydroxyacids); skin protectants; solvents; sunscreens; and surfactants. These are added in an amount of 0.5-40%. See page 16 in an amount of 0.5-40%. The examples

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disclose the use of an antioxidant (tocopheryl acetate) in an amount of 0.3%. Further, the composition can contains 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters. See page 16.

Krzysik discloses several examples:

The composition may comprise about 42 weight percent polyethylene 200 (compatibilizing agent), about 20 weight percent polyethylene glycol 8000 (immobilizing agent); about 10 weight percent behenyl alcohol (immobilizing agent); about 10 weight percent stearyl alcohol, about 5 weight percent glycerin (humectant), about 5 weight percent glycol stearate SE (dispersing agent), about 3 weight percent soy sterol, and about 5 weight percent evening primrose oil (natural oil). see page 9, lines 285-291.

Formula 6 discloses a composition comprising 35% PPG (compatibilizing agent); 20% PEG-8000 (immobilizing agent); 5% glycerin (humectant); 10% benzyl alcohol (immobilizing agent); 10% stearyl alcohol; 3% glyceryl stearate (dispersing agent); 3% sunflower oil (natural oil); 3% soy sterol; 10% dimethicone (emollient); 1% DC 1428.

Note with regard to claims 28-30 and 57-59, although the prior art does not explicitly recite this property, it is the examiner's position that the prior art will have the same properties since the prior art and the instant claims are the same. Note MPEP 2112.01 II: A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

(D) Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al.

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The disclosure of Krzysik et al has been delineated above. Krzysik et al teach using about 1 to about 20% of an emulsifying surfactant having an HLB range greater than 7 and 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal); and fatty esters.

Krzysik does not specifically teach the instantly claimed 1 to 1 ratio of silicone to dispersing agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the ratio of silicone to dispersing agent in view of the guidance provided by Krzysik et al. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(E) Claims 23-24 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al in view of Elias et al (5,643,899).

The disclosure of Krzysik et al has been delineated above. Krzysik teaches the use of various actives in the skin barrier composition such as natural moisturizing agents and skin protectant that protect injured or exposed skin and mucous membrane. See page 16.

Krzysik et al do not teach glucosylceramide.

Elias teaches irritations of the skin and mucous membrane caused by disrupted or dysfunctional epidermal barrier are treated or prevented by topical application of a formulation comprising epidermal lipid species such as cholesterol, an acylceramide, a ceramide, and

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essential and nonessential fatty acids. Elias teaches these combinations are effective both as moisturizing agents and agents for the restoration of barrier function and may be further enhanced by the use of known moisturizers such as petrolatum and glycerin. See abstract. The acylceramide in the composition may be replaced by a glycoceramide such as glucosylceramide. See column 5, lines 45-50, examples, and 13-14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Krzysik et al and Elias et al and further add a glucosylceramide in the Krzysik's skin barrier composition. One would have been motivated to add glucosylceramide with the expectation of success since Elias teaches the use of natural lipid species treats and prevents damage to the skin and mucous membrane and Krzysik teaches the additional use of active agents such as natural moisturizing agents and skin protectants that protect the skin and mucous membrane.

(F) Claims 14 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al in view of Mitchnick et al (6,103,267).

The disclosure of Krzysik et al has been delineated above. Krzysik teaches the use of an emulsifying surfactant having an HLB range greater than 7. Krzysik teaches the surfactant may be glyceryl stearate, glycol stearate, or an emulsifying wax. See page 5, second paragraph. Formula 6 utilizes glyceryl stearate and DC 1428 (a silicone gum surfactant).

Krzysik et al do not teach the instant surfactant (dispersing agent). Mitchnick teaches a dispersion comprising at least one water-soluble component and oily components such as silicone. See abstract. Mitchnick teaches the water-in-silicone dispersions comprise from about 0.5% to about 7.5% and more preferably from about 1% to about 5%, of an

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surface active agent for dispersing the discontinuous aqueous phase into the continuous silicone phase. Mitchnick teaches a wide variety of surface active agents may be employed and known and conventional emulsifiers/surfactants that provide the dispersion characteristics include non-silicone-containing emulsifiers/surfactants, silicone emulsifiers/surfactants, and mixtures thereof. Mitchnick teaches a wide variety of silicone surface-active agents within the low HLB range are useful. The silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene oxide and propylene oxide. Nonlimiting examples of dimethicone copolyols and other silicone surfactants useful as emulsifiers herein include polydimethylsiloxane polyether copolymers with pendant polyethylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed polyethylene oxide and polypropylene oxide sidechains, polydimethylsiloxane polyether copolymers with pendant mixed poly(ethylene)(propylene)oxide sidechains, etc. Examples of commercially available dimethicone copolyols include Dow Corning 190, 193, Q2-5220, 2501 Wax, 2-5324 fluid, and 3225C. Non-silicone emulsifiers include glyceryl stearate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Krzysik et al and Mitchnick et al and utilize the instant surfactant. One would have been motivated to utilize any known surfactant known to those skilled in the art since Mitchnick teaches the functional equivalency of the surfactants taught in

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Krzysik (glyceryl stearate) and the instant surfactant. Further, Krzysik teaches the use of a silicone emulsifier (DC 1428). Thus, the substitution of the prior art's surfactants with the instant silicone surfactant would have been obvious to those skilled in the art in view of Mitchnick's teachings. A skilled artisan would have reasonably expected success in the instant combination since Krzysik's teaches surfactants with an HLB of less than 7 and Mitchnick teaches the silicone surfactants have low HLBs.

(G) Claims 1-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30, 32-60 of copending Application No. 10/659969 and claims 1-59 of 10/659862. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the

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components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659862 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659862 independent claim 31 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659969 is directed to a absorbent substrate comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1%

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to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Copending 10/659969 independent claim 32 is directed to a tissue paper comprising a moisturizing and lubricating composition comprising from about 1% to about 40% of an silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

The difference between the instant claims and those claimed in the copending application is '969 and '862 are directed to absorbent products whereas the instant claims are directed to a composition. However, the instant claims and copending applications are obvious over each other since the absorbent products claimed in '969 and '862 comprise the instant composition. Further, it should be noted that the dependent claims and the copending dependent claims are substantially similar in scope, i.e. the same emollient, the same immobilizing agent, the same compatibilizing agent, and the same humectants are claimed.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(H) Claims 1-10, 12-13, 25-32, 34-41, 43, 52-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-33 US 5,869,075. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient (A), from about 1% to about 20% of a humectant (B), from about 30% to about 90% an immobilizing agent (C), and from about 1% to about 40% of a compatibilizing agent (D) wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

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US '075 independent claim 16 is directed to a softening composition comprising from about 30 to about 90 weight percent hydrophilic solvent (D), from about 10 to about 50 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (C), and from about 5 to about 40 weight percent of a C.sub.14 to C.sub.30 fatty alcohol (A), said composition having a melting point from about 30.degree. C. to about 70.degree. C. and a penetration hardness of from about 5 millimeters to about 360 millimeters. Claim 17 is directed to the hydrophilic solvents selected from the group consisting of water, propylene glycol, low molecular weight polyethylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate and silicone glycol. Dependent claim 23 is directed to the composition comprising about 15 weight percent propylene glycol (D), about 50 weight percent high molecular weight polyethylene glycol (C), about 10 weight percent cetyl alcohol (A), and about 25 weight percent hydrogenated starch hydrolysate (B). Dependent claim 29 is directed to a composition comprising about 35 weight percent propylene glycol (D), about 20 weight percent high molecular weight polyethylene glycol (C), about 10 weight percent behenyl alcohol (C), about 10 weight percent stearyl alcohol, about 10 weight percent of a mixture of glyceryl and glyceryl polyacrylate (B), and about 10 weight percent dimethicone (A). Dependent claim 30 is directed to a composition comprising about 30 weight percent propylene glycol, about 15 weight percent high molecular weight polyethylene glycol, about 10 weight percent behenyl alcohol, about 10 weight percent stearyl alcohol, about 15 weight percent hydrogenated starch hydrolysate, about 5 weight percent of a mixture of glyceryl polyacrylate, propylene glycol, cyclomethicone, dimethiconol, and polysorbate 20 (dispersing agent), and about 10 weight percent dimethicone.

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The difference between the instant claims and those claimed in the US '075 is US '075 independent claim 16 does not claim a the instant combination of (A), (B), (C), and (D). However, the dependent claims claim the instant combination. With regard to instant claim 31, US '075 does not claim the instant silicone emollient. However, dependent claims claim dimethicone in the same weight percent and thus rendering similar subject matter as claimed in claim 31. Therefore, the instant claims and US '075 are directed to similar subject matter.

(I) Claims 1, 4-10, 13, 1517, 21-22, 25, 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of US 6475197 Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant application is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of an emollient, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, and from about 1% to about 40% of a compatibilizing agent wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Independent claim 31 is directed to a moisturizing and lubricating composition comprising from about 1% to about 40% of a silicone, from about 1% to about 20% of a humectant, from about 30% to about 90% an immobilizing agent, from about 1% to about 40% of a compatibilizing agent, and a dispersing agent, wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are

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solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

US '197 claims body facing material having an outer surface, wherein said outer surface of said body facing material has a composition that enhances skin barrier consisting of: from about 10 to about 90 weight percent hydrophilic solvent (D); from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (C); from about 1 to about 30 weight percent of a C.sub.14 to C.sub.30 or greater fatty alcohol (A); from about 0.5 to about 10 weight percent of humectant (B); from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7; from about 0.1 to about 10 weight percent of sterol or sterol derivative; and, from about 0.1 to about 30 weight percent of natural fats or oils. Claim 2 is directed to a composition that has a melting point from about 30.degree. C. to about 100.degree. C. Claim 4 is directed to a composition that has a penetration hardness of from about 5 millimeters to about 360 millimeters. The dependent claims are directed to the instant humectant (glycerin), PEG with the instant molecular weight; PPG as the compatibilizing agent, the instant sterols, and instant fats and oils.

The difference between the instant claims and the claims of US '197 is US '197 directed to absorbent products whereas the instant claims are directed to a composition. However, the instant claims and copending applications are obvious over each other since the product comprise the instant composition.

(10) Response to Argument

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(A) Claims 1-4, 8-10, 12-13, 15-16, 25-31, 34-35, 39-41, 43-45, 52-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Krzysik (5,869,075).

Appellant argues that Krzysik fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Appellant argues these limitations are not inherent in Krzysik. Appellant argues that Krzysik states that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature. Thus, appellant concludes that the compositions of Krzysik *may* thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature) and thus the instant limitations cannot be said to be inherent. Appellant argues that the examples either lack the claimed components or comprises amount of one or more components that fall outside the claimed range.

Appellant's arguments are not persuasive for the following reasons:

Claim 1 is directed to a moisturizing and lubricating composition **comprising**:

- (a) from about 1% to about 40% of an emollient,
- (b) from about 1% to about 20% of a humectant,
- (c) from about 30% to about 90% of an immobilizing agent, and
- (d) from about 1% to about 40% of a compatibilizing agent,

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wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Summarily Example 7 of Krzysik discloses: a composition comprising:

(a) 10% of a dimethicone copolyol (specifically Dow Corning 190), which reads on claimed silicone emollient,

Page 20 of the instant specification discloses the suitable emollients: "Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are not limited to, petroleum based emollients, fatty acids, fatty acids esters, vegetable oils, hydrogenated vegetable oils, alkyl ethoxylates, fatty alcohols and silicones such as **dimethicone**, **dimethiconol**, **PEG dimethicone**, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof. Preferred emollients include **silicone based emollients** such as Dow Corning 200 Fluids and Dow Corning 1503 Fluids." Pages 21-24 discuss each emollient specifically.

(b) 20% hydrogenated starch hydrolysate, which reads on humectant,

Page 24 of the instant specification discloses the suitable humectants: "Suitable humectants for inclusion in the moisturizing and lubricating compositions of the present invention include urocanic acid, N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, glycerin, honey, hydrogenated honey, **hydrogenated starch hydrolysates**, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, polysaccharides, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid."

(c) 20% PEG-1000 and 30% PEG-8000, which read on immobilizing agents,

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Page 25 to 26 of the instant specification disclose suitable immobilizing agents: "Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include metal soaps including aluminum, calcium, magnesium, and zinc stearates, C.sub.14-C.sub.22 fatty alcohols, C.sub.12-C.sub.22 fatty acids, solid fatty acid esters, C.sub.12-C.sub.22 fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight (greater than about 720) polyethylene glycols (a polymer of ethylene oxides) that are solids at room temperature having the following empirical formula: $H(OCH_2CH_2)_xOH$ wherein x is the degree of ethoxylation and is an average value of at least about 20 moles or greater. Preferably, x is an average value of from about 20 to about 1,000, and even more preferably from about 100 to about 500. Particularly preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of **PEG 1000** (where x=20), **PEG 3350** (where x=75), **PEG 6000** (where x=125), **PEG 8000** (where x=150), and **PEG 10,000** (where x=220). Preferred fatty alcohol immobilizing agents include C.sub.16-C.sub.18 fatty alcohols and fatty acids such as myristyl, cetyl, cetearyl, stearyl, behenyl alcohols and acids, and mixtures thereof."

(d) 10% propylene glycol and 10% PEG-400, which read on compatibilizing agents;

Page 27 of the instant specification discloses suitable compatibilizing agents: "The compatibilizing agent may be selected from **propylene glycol**, butylene glycol, 1,3 butylene glycol, low molecular weight **polyethylene glycols (molecular weights of less than about 720** and liquid at room temperature such as, for example, PEG 600), methoxyisopropanol, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, and soluble/dispersible polypropylene glycols."

Regarding the recitation, "wherein no more than **about** 50% of the components are liquid at room temperature, 10% dimethicone copolyol (liquid, no melting point temperature as noted on King Corp homepage), 10% propylene glycol (melting point at -59°C), 10% PEG-400 (melting point 4-8°C), and 20% hydrogenated starch hydrolysate (syrup), are liquid at room temperature. Thus, 50% of the components are liquid at room temperature, i.e. no more than about 50% of the components are liquid at room temperature.

Regarding the recitation, "and no less than **about** 50% of the components are solid at room temperature, 20% PEG-1000 (melting point 40-41°C) and 30% PEG-8000 (melting point

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58-65°C), are solid at room temperature. Thus, 50% of the components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature.

Regarding the recitation, “at least *about* 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, all the components in example 7 are water-soluble including dimethicone copolyol. Dimethicone copolyol is a silicone derived emollient that also is a surfactant (surfactant has hydrophilic and hydrophobic properties wherein the dimethicone imparts the hydrophobic properties and the polyol imparts the hydrophilic properties). Thus, all the components form a single phase. Assuming arguendo that dimethicone copolyol is considered to form another phase (although this is highly unlikely due to its surfactant properties), it is utilized in a weight percent of 10%. The requirement that about 85% of the components form a single phase is satisfied. Furthermore, Example 7 discloses that the composition has a melting point of about 29°C. Thus, if the *entire composition* has a melting point of 29°C and all the components are water-soluble as discussed above, then it is implicit that the composition will form a single phase at a temperature of about 45°C to about 85°C.

Secondly, from appellant’s arguments, it is clear from appellant’s arguments that forming a “single phase” merely requires all the components are melted at that temperature. Thus, PEG-400 (melting point of 4-8°C); PEG-1000 (melting point 40-41°C); PEG-8000 (melting point 58-65°C); dimethicone copolyol (a liquid, does not have a melting point), hydrogenated starch hydrolysate (HSH is a syrup) are all in a melted form at a temperature of *about* 45°C to *about* 80°C.

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It is noted that although the prior art does not explicitly disclose the instant functional limitation, the examiner respectfully submits that the prior art need not explicitly recite a property to anticipate the instant invention. The prior art teaches the same components in the same weight percent and therefore the claimed properties, must be the same since "A chemical composition and its properties are inseparable." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner further respectfully submits that the examiner has made a reasonable rationale for inherency with regard to the claimed functional limitations. As noted in MPEP 2112, the examiner is required to show and reasonable rationale for inherency and then the burden shifts to applicant to show the difference. In instant case, it is the examiner's position that the examiner has provided a reasonable rationale of inherency; however appellant has not provided any evidence showing the contrary. The examiner respectfully submits that "attorney's arguments cannot take the place of evidence." MPEP 716.01(c).

Appellant argues that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature.

However, the examiner respectfully submits that the general disclosure is not relied upon to make the anticipation rejection. Rather example 7, as explained above, it relied upon.

Appellant argues that the novelty of the instant invention lies in the fact that the composition does not migrate off of the substrate during storage.

The examiner respectfully points out that Krzysik also discloses a lotion that is retained on a soft tissue on column 1 and 2.

Appellant argues that none of the examples teach 1-20% of a humectant and the amount taught exceeds this amount. Appellant argues that propylene glycol, glycerin, and sodium hydrolysates act as humectants.

Firstly, the examiner points out that the instant claim language, i.e. “comprising”, does not exclude other components in the composition. As set forth in MPEP 2111.03, [t]he transitional term “comprising” which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and **does not exclude additional, unrecited elements**”.

Secondly, the examiner points out that the claims requires from about 1% to about 40% of a compatibilizing agent and about 1 to about 20% of a humectant. Example 7 discloses hydrogenated starch hydrolysate, which reads on humectants as defined the specification on page 24. Thus, the limitation of about 1-20% of a humectant is satisfied. Example 7 further discloses 10% propylene glycol and 10% PEG-400, both of which read on compatibilizing as defined in the specification page 27. Therefore, the limitation of about 1-40% of a compatibilizing agent is met.

Appellant argues that although propylene glycol is identified as a compatibilizing agent, only polyethylene glycols with a molecular weight of less than 720 and are liquid at room temperature are suitable as a compatibilizing agent.

Appellant’s arguments are unclear since appellant clearly acknowledges that propylene glycol is a suitable compatibilizing agent, which the examiner has not disputed. Further, the

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examiner has not disputed the fact that appellant's disclosure discloses polyethylene glycols with a molecular weight of less than 720 are also suitable compatibilizing agents. Hence, it is the examiner's position that example 7 which discloses 10% propylene glycol and 10% PEG-400, anticipates the instant invention.

Appellant argues that example 7 of the prior art has a penetration hardness of about 238 millimeters. Appellant argues that although claim 1 does not claim a penetration hardness, the desirable hardness is about 1 to about 200 millimeters.

As acknowledged by appellant, claim 1 does not claim this property. Therefore, this argument is moot. However, the examiner does note column 2, lines 44-55 wherein Krzysik discloses:

In addition, for purposes herein, "penetration hardness" is the needle penetration in millimeters according to ASTM D 1321, "Needle Penetration of Petroleum Waxes. Lower needle penetration hardness values correspond to harder materials. The penetration hardness of the compositions of this invention can be from about 5 to 360 millimeters, more specifically from about 5 to about 200 millimeters, more specifically from about 5 to about 150 millimeters, and still more specifically from about 5 to about 100 millimeters. (Formulations having a needle penetration hardness greater than 360 millimeters cannot be measured using ASTM method D 1321). The hardness of the formulations of this invention is important for two reasons. First, the softer the formulation the more mobile the formulation will be, making the formulation more likely to migrate to the inner plies of the tissue, which is not desirable. Secondly, softer formulations tend to be more greasy/oily to the touch, which is also less desirable. In general, formulations having a needle penetration hardness of from about 200 to 360 millimeters feel creamy to slightly greasy with less smoothness (depending on additives). Formulations that have needle penetration hardness values of from about 5 to about 200 millimeters feel silky to creamy and very smooth (depending on additives).

Lastly, the examiner respectfully points out that appellant's disclosure does not define the term "about" to mean exactly. MPEP 2111.01 (IV).

Appellant argues the merits of the other examples.

The examiner respectfully submits that only one example needs to anticipate the rejection. However, the examiner will provide the analysis for example 11.

a) 10% of a dimethicone and 5% myristyl myristate, which equals 35% of emollients,

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Page 20 of the instant specification discloses the suitable emollients: "Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are not limited to, petroleum based emollients, fatty acids, **fatty acids esters**, vegetable oils, hydrogenated vegetable oils, alkyl ethoxylates, **fatty alcohols** and silicones such as **dimethicone**, dimethiconol, PEG dimethicone, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof. Preferred emollients include silicone based emollients such as Dow Corning 200 Fluids and Dow Corning 1503 Fluids." Pages 21-24 discuss each emollient specifically.

(b) 10% Hispagel 200, which is a hydrogel humectant derived from glycerin (it should be noted that glycerin is a known humectant), which reads on humectant,

Page 24 of the instant specification discloses the suitable humectants: "Suitable humectants for inclusion in the moisturizing and lubricating compositions of the present invention include urocanic acid, N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, **glycerin**, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, polysaccharides, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid."

(c) 20% PEG-8000, 10% stearyl alcohol, and 10% behenyl alcohol, which read on immobilizing agents,

Page 25 to 26 of the instant specification disclose suitable immobilizing agents: "Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include metal soaps including aluminum, calcium, magnesium, and zinc stearates, C.sub.14-C.sub.22 fatty alcohols, C.sub.12-C.sub.22 fatty acids, solid fatty acid esters, C.sub.12-C.sub.22 fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight (greater than about 720) polyethylene glycols (a polymer of ethylene oxides) that are solids at room temperature having the following empirical formula: $H(OCH_{2.2}CH_{2.2})_{x}OH$ wherein x is the degree of ethoxylation and is an average value of at least about 20 moles or greater. Preferably, x is an average value of from about 20 to about 1,000, and even more preferably from about 100 to about 500. Particularly

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preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of PEG 1000 (where $x=20$), PEG 3350 (where $x=75$), PEG 6000 (where $x=125$), **PEG 8000** (where $x=150$), and PEG 10,000 (where $x=220$). Preferred fatty alcohol immobilizing agents include C.sub.16-C.sub.18 fatty alcohols and fatty acids such as myristyl, cetyl, cetearyl, **stearyl, behenyl alcohols** and acids, and mixtures thereof.”

(d) 35% propylene glycol and 10% PEG-400, which read on compatibilizing agents;

Page 27 of the instant specification discloses suitable compatibilizing agents: “The compatibilizing agent may be selected from **propylene glycol**, butylene glycol, 1,3 butylene glycol, low molecular weight **polyethylene glycols (molecular weights of less than about 720** and liquid at room temperature such as, for example, PEG 600), methoxyisopropanol, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, and soluble/dispersible polypropylene glycols.”

The entire composition has a melting point of 53-60°C and a needle penetration of 20-130 millimeters.

Appellant argues that in example 11 does not disclose the instant limitation of “at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.” Appellant argues that propylene glycol has a melting point of -59°C; behenyl alcohol has a melting point of 65-73°C; stearyl alcohol has a melting point of 61°C, and PEG-8000 has a melting point of 61°C. Thus, appellant argues that since the melting point for all of these components is above 45°C, at least some portion of these components should be solid at the lower end of the 45°C to 80°C temperature range. Therefore, appellant argues that it cannot be said that at least about 85% (by weight) of the components of the formulation of Example 11 will form a single phase at the composition's melting point.

The claim requires that at least about 85% of the components form a single phase at a temperature of from about 45°C to about 80°C. Firstly, it is clear from appellant's arguments

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that forming a "single phase" merely requires all the components are melted at that temperature.

Secondly, appellant acknowledges that at least 75% of the components melt to form a single phase about 45°C to about 80°C. Propylene glycol has a melting point of -59°C; behenyl alcohol has a melting point of 65-73°C; stearyl alcohol has a melting point of 61°C, and PEG-8000 has a melting point of 61°C. The examiner points out that dimethicone is liquid and does not have a melting temperature (see Wikipedia). Example 11 discloses 10% dimethicone. Thus, dimethicone being a liquid, would still be liquid at about 45°C to about 80°C. Thus, at least about 85% of the components are in a liquid, melted form, to form a single phase about 45°C to about 80°C.

Additionally, the examiner points out that Example 11 contains 5% myristyl myristate, which has a melting point of 36-40°C melting point. It is noted that the claims use the term "about" and the specification does not disclose that the term "about" mean exactly. Thus, the term "about" has latitude. MPEP 2111.01 (IV). Thus, myristyl myristate's melting point of 36-40°C reads on the lower claimed range "about 45°C". Thus, 35% propylene glycol, 20% PEG-8000, 10% behenyl alcohol, 10% stearyl alcohol, 10% dimethicone, and 5% myristyl myristate equal at least 80% have a melting point of "about 45°C". At least 90% reads on the claimed range of "about 85%".

Therefore, for the above reasons it is the examiner's position that the prior art anticipates the instant invention.

(B) Claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Tyrell et al (20020120241).

Appellant argues that Tyrell fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Appellant argues these limitations are not inherent in Tyrell's disclosure. Appellant argues that Tyrell states that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature. Thus, appellant concludes that the compositions of Tyrell *may* thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature) and thus the instant limitations cannot be said to be inherent. Appellant argues that the examples either lack the claimed components or comprises amount of one or more components that fall outside the claimed range.

Appellant's arguments are not persuasive for the following reasons:

Claim 1 is directed to a moisturizing and lubricating composition **comprising**:

- (a) from about 1% to about 40% of an emollient,
- (b) from about 1% to about 20% of a humectant,
- (c) from about 30% to about 90% of an immobilizing agent, and
- (d) from about 1% to about 40% of a compatibilizing agent,

wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and at least about 85%

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(by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Firstly, it is noted that appellant does not discuss Example 13 in which the examiner's rejection is based. The examiner rejected the claims over Example 13 and 20. However, the examiner will discuss example 13 specifically.

Summarily Example 13 of Tyrell discloses: a composition comprising:

(a) 10% of a dimethicone, and 1% sunflower oil, which reads on emollient,

Page 20 of the instant specification discloses the suitable emollients: "Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are not limited to, petroleum based emollients, fatty acids, fatty acids esters, **vegetable oils**, hydrogenated vegetable oils, alkyl ethoxylates, fatty alcohols and silicones such as **dimethicone**, dimethiconol, PEG dimethicone, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof. Preferred emollients include **silicone based emollients** such as Dow Corning 200 Fluids and Dow Corning 1503 Fluids." Pages 21-24 discuss each emollient specifically.

(b) 5% hydrogenated starch hydrolysate and 1% chitosan (polysaccharide), which reads on humectant,

Page 24 of the instant specification discloses the suitable humectants: "Suitable humectants for inclusion in the moisturizing and lubricating compositions of the present invention include urocanic acid, N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, glycerin, honey, hydrogenated honey, **hydrogenated starch hydrolysates**, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, **polysaccharides**, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid."

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(c) 25% PEG-10,000 and 25% behenyl alcohol, which read on immobilizing agents,

Page 25 to 26 of the instant specification disclose suitable immobilizing agents: "Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include metal soaps including aluminum, calcium, magnesium, and zinc stearates, C.sub.14-C.sub.22 fatty alcohols, C.sub.12-C.sub.22 fatty acids, solid fatty acid esters, C.sub.12-C.sub.22 fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight (greater than about 720) polyethylene glycols (a polymer of ethylene oxides) that are solids at room temperature having the following empirical formula: $H(OCH_2CH_2)_xOH$ wherein x is the degree of ethoxylation and is an average value of at least about 20 moles or greater. Preferably, x is an average value of from about 20 to about 1,000, and even more preferably from about 100 to about 500. Particularly preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of PEG 1000 (where x=20), PEG 3350 (where x=75), PEG 6000 (where x=125), PEG 8000 (where x=150), and **PEG 10,000** (where x=220). Preferred fatty alcohol immobilizing agents include C.sub.16-C.sub.18 fatty alcohols and fatty acids such as myristyl, cetyl, cetearyl, stearyl, **behenyl alcohols** and acids, and mixtures thereof."

(d) 28% propylene glycol, which reads on compatibilizing agents;

Page 27 of the instant specification discloses suitable compatibilizing agents: "The compatibilizing agent may be selected from **propylene glycol**, butylene glycol, 1,3 butylene glycol, low molecular weight polyethylene glycols (molecular weights of less than about 720 and liquid at room temperature such as, for example, PEG 600), methoxyisopropanol, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, and soluble/dispersible polypropylene glycols."

The composition further contains % laureth-3 (dispersing agent); 3% laureth-4 (dispersing agent); 0.8% soy sterol, which read on dependent claims that require a dispersing agent and sterol.

Thus, example 13 of the prior art contains all the claimed components in the same weight percent.

Regarding the recitation, "wherein no more than **about** 50% of the components are liquid at room temperature, and no more than about 50% of the components, 28% propylene glycol (melting point of $-59^{\circ}C$), 10% dimethicone (does not have a melting point), 1% sunflower oil

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(-17°C), and 5% hydrogenated starch hydrolysate (syrup), are liquid at room temperature. Thus, 44% of the components are liquid at room temperature, i.e. no more than about 50% of the components are liquid at room temperature.

Regarding the recitation, “and no less than *about* 50% of the components are solid at room temperature, 0.8% soy sterol, 25% PEG-10,000 and 25% benzyl alcohol are solid at room temperature. Thus, 50.8% of the components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature.

The liquid or solid (at room temperature) property of 1% chitosan polymer, and 2% laureth-3, and 3% laureth-4 is unclear. However, the claimed recitation would still be met. For instance, if chitosan polymer, laureth-3, and laureth-4 are liquid at room temperature, then 50% of the components would still be liquid at room temperature. Thus still satisfying the limitation that no more than *about* 50% of the components are liquid at room temperature. If chitosan polymer, laureth-3, and laureth-4 are solid at room temperature, then 56% of the components would be solid at room temperature and thus still satisfying the limitation that no less than *about* 50% of the components are solid at room temperature.

Regarding the recitation, “at least *about* 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, as acknowledged by appellant propylene glycol has a melting point of -59°C, behenyl alcohol has a melting point of 65-73°C, and appellant states PEG-10,000 has a melting point of 64.8°C. Sunflower oil has a melting point of -17°C, starch hydrolysate (a syrup), and dimethicone is a liquid. Thus, the requirement that about 85% of the components melt to form a single phase is satisfied since about 93% of the components are in melted form at

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45°C to about 80°C. It is clear from appellant's arguments that forming a "single phase" merely requires all the components are melted at that temperature. It is noted that soy sterol has a melting point of above 100°C. However, only 0.8% is utilized.

It is noted that although the prior art does not explicitly disclose the instant functional limitation, the examiner respectfully submits that the prior art need not explicitly recite a property to anticipate the instant invention. The prior art teaches the same components in the same weight percent and therefore the claimed properties, must be the same since "A chemical composition and its properties are inseparable." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner further respectfully submits that the examiner has made a reasonable rationale for inherency with regard to the claimed functional limitations. As noted in MPEP 2112, the examiner is required to show a reasonable rationale for inherency and then the burden shifts to applicant to show the difference. In instant case, it is the examiner's position that the examiner has provided a reasonable rationale of inherency; however appellant has not provided any evidence showing the contrary. The examiner respectfully submits that "attorney's arguments cannot take the place of evidence." MPEP 716.01(c).

Appellant argues that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature.

However, the examiner respectfully submits that the general disclosure is not relied upon to make the anticipation rejection. Rather example 13, as explained above, it relied upon.

Appellant argues that the novelty of the instant invention lies in the fact that the composition does not migrate off of the substrate during storage.

The examiner respectfully points out that Tyrell also discloses a lotion that is retained on a substrate. See [0042].

Appellant argues that none of the examples the claimed amounts of each component.

This argument has been addressed substantially above. The examiner also points out that the instant claim language, i.e. “comprising”, does not exclude other components in the composition. As set forth in MPEP 2111.03, [t]he transitional term “comprising” which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and **does not exclude additional, unrecited elements**. However, the examiner points out that example 13 does not contain any additional components that are not claimed. As set forth above, 28% propylene glycol (compatibilizing agent); 5% hydrogenated starch hydrolysate (humectant); 1% chitosan polymer (polysaccharide humectant); 25% of PEG 10,000 (immobilizing agents); 25% benzyl alcohol (immobilizing agents); 2% laureth-3 (dispersing agent); 3% laureth-4 (dispersing agent); 10% dimethicone (emollient); 1% sunflower oil; 0.8% soy sterol (claim 22).

Appellant argues the merits of the other examples.

The examiner respectfully submits that only one example needs to anticipate the rejection. It is the examiner’s position that Example 13 anticipates the instant rejection.

Therefore, for the above reasons it is the examiner’s position that the prior art anticipates the instant invention.

(C) Claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, 57-59 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/64409 to Krzysik et al.

Appellant argues that Krzysik fails to disclose a composition wherein no more than 50% of the components are liquid at room temperature and no less than 50% of the components are solid at room temperature, and at least 85% of the components form a single phase. Appellant argues these limitations are not inherent in Krzysik. Appellant argues that Krzysik states that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature. Thus, appellant concludes that the compositions of Krzysik *may* thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature) and thus the instant limitations cannot be said to be inherent. Appellant argues that the examples either lack the claimed components or comprises amount of one or more components that fall outside the claimed range.

Appellant's arguments are not persuasive for the following reasons:

Claim 1 is directed to a moisturizing and lubricating composition **comprising**:

- (a) from about 1% to about 40% of an emollient,
- (b) from about 1% to about 20% of a humectant,
- (c) from about 30% to about 90% of an immobilizing agent, and
- (d) from about 1% to about 40% of a compatibilizing agent,

wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and at least about 85%

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(by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Summarily, examples on page 9 of Krzysik discloses: a composition comprising:

(a) about 5% of a primrose oil, which reads on emollient,

Page 20 of the instant specification discloses the suitable emollients: "Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are not limited to, petroleum based emollients, fatty acids, fatty acids esters, **vegetable oils**, hydrogenated vegetable oils, alkyl ethoxylates, fatty alcohols and silicones such as dimethicone, dimethiconol, PEG dimethicone, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof. Preferred emollients include silicone based emollients such as Dow Corning 200 Fluids and Dow Corning 1503 Fluids." Pages 21-24 discuss each emollient specifically.

(b) about 5% glycerin, which read on humectant,

Page 24 of the instant specification discloses the suitable humectants: "Suitable humectants for inclusion in the moisturizing and lubricating compositions of the present invention include urocanic acid, N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, **glycerin**, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, polysaccharides, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid."

(c) about 20% PEG-8000, 10% behenyl alcohol, 10% stearyl alcohol, which read on immobilizing agents,

Page 25 to 26 of the instant specification disclose suitable immobilizing agents: "Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include metal soaps including aluminum, calcium, magnesium, and zinc stearates, C.sub.14-C.sub.22 fatty alcohols, C.sub.12-C.sub.22 fatty acids, solid fatty acid esters, C.sub.12-

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C.sub.22 fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight (greater than about 720) polyethylene glycols (a polymer of ethylene oxides) that are solids at room temperature having the following empirical formula: $H(OCH_2CH_2)_xOH$ wherein x is the degree of ethoxylation and is an average value of at least about 20 moles or greater. Preferably, x is an average value of from about 20 to about 1,000, and even more preferably from about 100 to about 500. Particularly preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of PEG 1000 (where $x=20$), PEG 3350 (where $x=75$), PEG 6000 (where $x=125$), **PEG 8000** (where $x=150$), and PEG 10,000 (where $x=220$). Preferred fatty alcohol immobilizing agents include C.sub.16-C.sub.18 fatty alcohols and fatty acids such as myristyl, cetyl, cetearyl, **stearyl, behenyl alcohols** and acids, and mixtures thereof.”

(d) *about* 42% propylene glycol, which reads on compatibilizing agents (it is noted the prior art and the instant claims utilize the term “about” and the term about is not defined in the instant specification to mean exactly and thus is given latitude as noted in MPEP 2111.01 (IV));

Page 27 of the instant specification discloses suitable compatibilizing agents: “The compatibilizing agent may be selected from **propylene glycol**, butylene glycol, 1,3 butylene glycol, low molecular weight polyethylene glycols (molecular weights of less than about 720 and liquid at room temperature such as, for example, PEG 600), methoxyisopropanol, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, and soluble/dispersible polypropylene glycols.”

The composition further contains 5% glyceryl stearate (dispersing agent) and 3% soy sterol, which read on dependent claims that require a dispersing agent and sterol.

Thus, this embodiment contains all of the prior art contains all the claimed components in the same weight percent.

Regarding the recitation, “wherein no more than **about** 50% of the components are liquid at room temperature, 42% propylene glycol, 5% glycerin (18°C), 5% prim rose oil (liquid above 0°C), are liquid at room temperature. Thus, 52% of the components are liquid at room temperature, i.e. no more than **about** 50% of the components are liquid at room temperature. The examiner respectfully submits that the term “about” is not defined in the specification to mean

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exactly and thus “about” is given latitude. MPEP 2111.01 (IV). Thus, it is respectfully submitted that the prior art’s 52% reads on the instant “about 50%”.

Regarding the recitation, “and no less than **about** 50% of the components are solid at room temperature, 20% PEG-8000, 10% behenyl alcohol, and 10% stearyl alcohol, 5% glyceryl stearate (melting point 58°C), 3% soy sterol are solid at room temperature. Thus, 48% of the components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature. The examiner respectfully submits that the term “about” is not defined in the specification to mean exactly and thus “about” is given latitude. MPEP 2111.01 (IV). Thus, it is respectfully submitted that 48% reads on instant “about 50%”.

Regarding the recitation, “at least **about** 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, PEG-200 has a melting point of 4-5°C, behenyl alcohol has a melting point of 65-73°C, and appellant states PEG-8000 has a melting point of 61°C. Prim rose oil has a melting point above 0°C and glyceryl stearate has a melting point of 58°C. Thus, the requirement that about 85% of the components melt to form a single phase is satisfied since about 97% of the components are melted at 45°C to about 80°C. It is clear from appellant’s arguments that forming a “single phase” merely requires all the components are melted at that temperature. It is noted that soy sterol has a melting point of above 100°C. However, only 3% is utilized.

Similarly, Example 6 of Krzysik discloses: a composition comprising:

(a) 10% of a dimethicone, 3% sunflower oil, which read on claimed silicone emollient,

Page 20 of the instant specification discloses the suitable emollients: “Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are

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not limited to, petroleum based emollients, fatty acids, fatty acids esters, vegetable oils, hydrogenated vegetable oils, alkyl ethoxylates, fatty alcohols and silicones such as **dimethicone**, **dimethiconol**, **PEG dimethicone**, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof. Preferred emollients include **silicone based emollients** such as Dow Corning 200 Fluids and Dow Corning 1503 Fluids.” Pages 21-24 discuss each emollient specifically.

(b) 5% glycerin, which read on humectant,

Page 24 of the instant specification discloses the suitable humectants: “Suitable humectants for inclusion in the moisturizing and lubricating compositions of the present invention include urocanic acid, N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, **glycerin**, honey, hydrogenated honey, **hydrogenated starch hydrolysates**, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, polysaccharides, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid.”

(c) 20% PEG-8000, 10% behenyl alcohol, 10% stearyl alcohol, which read on immobilizing agents,

Page 25 to 26 of the instant specification disclose suitable immobilizing agents: “Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include metal soaps including aluminum, calcium, magnesium, and zinc stearates, C.sub.14-C.sub.22 fatty alcohols, C.sub.12-C.sub.22 fatty acids, solid fatty acid esters, C.sub.12-C.sub.22 fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight (greater than about 720) polyethylene glycols (a polymer of ethylene oxides) that are solids at room temperature having the following empirical formula: $H(OCH_2CH_2)_xOH$ wherein x is the degree of ethoxylation and is an average value of at least about 20 moles or greater. Preferably, x is an average value of from about 20 to about 1,000, and even more preferably from about 100 to about 500. Particularly preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of PEG 1000 (where x=20), PEG 3350 (where x=75), PEG 6000 (where x=125), **PEG 8000** (where x=150), and PEG 10,000 (where x=220). Preferred fatty alcohol immobilizing

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agents include C.sub.16-C.sub.18 fatty alcohols and fatty acids such as myristyl, cetyl, cetearyl, **stearyl, behenyl alcohols** and acids, and mixtures thereof.”

(d) 35% propylene glycol, which reads on compatibilizing agents;

Page 27 of the instant specification discloses suitable compatibilizing agents: “The compatibilizing agent may be selected from **propylene glycol**, butylene glycol, 1,3 butylene glycol, low molecular weight **polyethylene glycols (molecular weights of less than about 720** and liquid at room temperature such as, for example, PEG 600), methoxyisopropanol, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, and soluble/dispersible polypropylene glycols.”

The composition further contains 3% glyceryl stearate (dispersing agent); DC1428 1% (dispersing agent); 3%% soy sterol, which read on dependent claims that require a dispersing agent and sterol.

Thus, example 6 of the prior art contains all the claimed components in the same weight percent.

Regarding the recitation, “wherein no more than **about** 50% of the components are liquid at room temperature, 35% propylene glycol, 5% glycerin (18°C), 3% sunflower oil, and 10% dimethicone, are liquid at room temperature. Thus, 53% of the components are liquid at room temperature, i.e. no more than **about** 50% of the components are liquid at room temperature. The examiner respectfully submits that the term “about” is not defined in the specification to mean exactly and thus “about” is given latitude. MPEP 2111.01 (IV). Thus, it is respectfully submitted that the prior art’s 53% reads on the instant “about 50%”.

Regarding the recitation, “and no less than **about** 50% of the components are solid at room temperature, 20% PEG-8000, 10% behenyl alcohol, and 10% stearyl alcohol, 3% glyceryl stearate (melting point 58°C), 3% soy sterol are solid at room temperature. Thus, 46% of the

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components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature. The examiner respectfully submits that the term “about” is not defined in the specification to mean exactly and thus “about” is given latitude. MPEP 2111.01 (IV). Thus, it is respectfully submitted that the prior art’s 46% reads on the instant “about 50%”.

Regarding the recitation, “at least *about* 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, as acknowledged by appellant propylene glycol has a melting point of -59°C, behenyl alcohol has a melting point of 65-73°C, and appellant states PEG-8000 has a melting point of 61°C. Sunflower oil has a melting point of -17°C, glycerin has a melting point of 18°C, and dimethicone is a liquid. Glyceryl stearate has a melting point of 58°C. Thus, the requirement that about 85% of the components melt to form a single phase is satisfied since about 96% of the components are melted at 45°C to about 80°C. It is clear from appellant’s arguments that forming a “single phase” merely requires all the components are melted at that temperature. It is noted that soy sterol has a melting point of above 100°C. However, only 3% is utilized.

The embodiment on page 9, lines 285-291 should also be noted. However, for brevity sake, the examiner will not further analyze this embodiment.

Although the examples disclosed by the prior art do not explicitly disclose the instant functional limitation, the examiner respectfully submits that the prior art need not explicitly recite a property to anticipate the instant invention. The prior art teaches the same components in the same weight percent and therefore the claimed properties, must be the same since “A

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chemical composition and its properties are inseparable.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner further respectfully submits that the examiner has made a reasonable rationale for inherency with regard to the claimed functional limitations. As noted in MPEP 2112, the examiner is required to show a reasonable rationale for inherency and then the burden shifts to applicant to show the difference. In instant case, it is the examiner’s position that the examiner has provided a reasonable rationale of inherency; however appellant has not provided any evidence showing the contrary. The examiner respectfully submits that, “attorney’s arguments cannot take the place of evidence.” MPEP 716.01(c).

Appellant argues that the general disclosure discloses that the compositions disclosed therein comprise from about 30 to about 90% of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature.

However, the examiner respectfully submits that the general disclosure is not relied upon to make the anticipation rejection. Rather example 6, as explained above, it relied upon.

Appellant argues that the novelty of the instant invention lies in the fact that the composition does not migrate off of the substrate during storage.

The examiner respectfully points out that Krzysik also discloses a lotion that is retained on a soft tissue.

Appellant argues that none of the examples the claimed amounts of each component.

This argument has been addressed substantially above. The examiner also points out that the instant claim language, i.e. “comprising”, does not exclude other components in the

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composition. As set forth in MPEP 2111.03, [t]he transitional term “comprising” which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and **does not exclude additional, unrecited elements**. However, the examiner points out that example 6 does not contain any additional components that are not claimed. As set forth above, 35% PPG (compatibilizing agent); 20% PEG-8000 (immobilizing agent); 5% glycerin (humectant); 10% benzyl alcohol (immobilizing agent); 10% stearyl alcohol (immobilizing agent); 3% glyceryl stearate (dispersing agent); 3% sunflower oil (emollient oil); 3% soy sterol (claim 22); 10% dimethicone (emollient); 3% glyceryl stearate (dispersing agent), 1% DC 142828 (reads on dispersing agent or emollient). Similarly, the embodiment on page 9 does not contain any additional components other than those claimed in the independent and dependent claims. The composition comprises about 42 weight percent polyethylene 200 (compatibilizing agent), about 20 weight percent polyethylene glycol 8000 (immobilizing agent); about 10 weight percent behenyl alcohol (immobilizing agent); about 10 weight percent stearyl alcohol (immobilizing agent), about 5 weight percent glycerin (humectant), about 5 weight percent glycol stearate SE (dispersing agent), about 3 weight percent soy sterol (claim 22), and about 5 weight percent evening primrose oil (emollient).

Therefore, for the above reasons, it is the examiner’s position that the prior art anticipates the instant invention.

(D) Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al.

Appellant’s arguments are similar to those made regarding the anticipation rejection.

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Appellant argues that modifications will depart from the claimed limitations in the independent claims.

Appellant's arguments are not persuasive for the following reasons:

The examiner has addressed the merits of WO 006409 above, which is incorporated herein. Summarily Example 6 of Krzysik discloses: a composition comprising:

(a) 10% of a dimethicone, 3% sunflower oil, which read on claimed silicone emollient,
(b) 5% glycerin, which read on humectant,
(c) 20% PEG-8000, 10% behenyl alcohol, 10% stearyl alcohol, which read on immobilizing agents,

(d) 35% propylene glycol, which reads on compatibilizing agents;

(e) 53% of the components are liquid at room temperature, i.e. no more than **about** 50% of the components are liquid at room temperature. The examiner respectfully submits that the term "about" is not defined in the specification to mean exactly and thus "about" is given latitude. MPEP 2111.01 (III).

(f) 46% of the components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature. The examiner respectfully submits that the term "about" is not defined in the specification to mean exactly and thus "about" is given latitude. MPEP 2111.01 (III).

The composition further contains 3% glyceryl stearate (dispersing agent); DC1428 1% (dispersing agent); 3%soy sterol, which read on dependent claims that require a dispersing agent and sterol.

Therefore, WO 00/64409 is only deficient in the instantly claimed weight ratio of silicone to dispersing agent. Example 6 discloses 10% dimethicone and 4% of dispersing agents (3% glyceryl stearate and DC 1428). However, the general disclosure teaches that about 1 to about 20% of an emulsifying surfactant having an HLB range greater than 7 can be utilized and 0.01-20% of an oil soluble or lipophilic ingredient including silicones, oils (mineral, vegetable, and animal) may be utilized. Thus, for a skilled artisan to manipulate the ration of silicone to dispersing agent without providing any evidence of unobviousness (which appellant has not done), is prima facie obvious. Especially, in light of the fact that the prior art provides a general guidance to do so. For instance, 10% dimethicone is taught and 4% dispersing agent is disclosed. Krzysik teaches the emulsifier may be used in an amount of 10 (1-20% is the general range), then the 1:1 ratio is satisfied.

Regarding appellant's argument that modification would depart from the claimed limitation in the independent claims, the examiner respectfully disagrees. Firstly, claim 30 does not limit the amount of the dispersing agent. Regarding the recitation, "wherein no more than *about* 50% of the components are liquid at room temperature, 35% propylene glycol, 5% glycerin (18°C), 3% sunflower oil, and 10% dimethicone, are liquid at room temperature, the increase in glyceryl stearate would not change this amount. Thus, 53% of the components are liquid at room temperature.

Regarding the recitation, "and no less than *about* 50% of the components are solid at room temperature, 20% PEG-8000, 10% behenyl alcohol, and 10% stearyl alcohol, 10% glyceryl stearate (melting point 58°C), 3% soy sterol are solid at room temperature. Thus, 53% of the

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components are solid at room temperature, i.e. no less than about 50% of the components are solid at room temperature.

Regarding the recitation, "at least *about* 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, all the components except for soy sterol, which is used only in an amount of 3%, are in a melted form as acknowledged by appellant propylene glycol has a melting point of at 45°C to about 80°C.

Furthermore, the manipulation of such factors within the guidelines provided by the prior art, is prima facie obvious to one of ordinary skill in the art. The addition or conversely, the subtraction of optional components is done within the parameter of maintaining the composition on the substrate, i.e. Krzysik's tissue, as taught by Krzysik.

Therefore, for the reasons given above, it is the examiner's position that the instant claims are rendered prima facie obvious.

(E) Claims 23-24 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al in view of Elias et al (5,643,899).

Appellant's arguments are similar to those made regarding the anticipation rejection. Appellant argues that Elias does not cure Krzysik's deficiency in the disclosure of a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase.

Appellant's arguments are not persuasive for the following reasons:

The examiner has addressed the merits of WO 00/6409 above, which is incorporated

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herein. As discussed above, it is the examiner's position that WO 00/64409 is not deficient in the required limitations of the independent claims. WO 00/64409 is only deficient in the teaching of the incorporation of the claimed glucosylceramide. Therefore, Elias is not relied upon to teach a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase since Krzysik is not deficient in this sense. Elias teaches the use of natural lipid species treats and prevents damage to the skin and mucous membrane and Krzysik teaches the additional use of active agents such as natural moisturizing agents and skin protectants. Therefore, a skilled artisan would have been motivated to add glucosylceramide to protect the skin from damage. Appellant has not addressed the examiner's motivation.

The examiner further respectfully points out that the instant modification would not depart from the claimed limitation in the independent claims. For instance, Krzysik teaches 3% soy sterol but also discloses on page 12, "sterols" may include soy sterol, cholesterol, etc. Elias teaches a combination of cholesterol and glucosylceramide in a ratio of 0.25:1 to 5:1. Thus, if the glucosylceramide was incorporated in an amount of 5:1 ratio. The sterol would be in a concentration of 3% as taught and glucosylceramide would be in a concentration of 0.6%. Adding 0.6% glucosylceramide, which has a melting point of above 100 °C (the exact melting point is not know), Krzysik's composition would still satisfy the required limitations of the independent claims. Furthermore, the manipulation of such factors within the guidelines provided by the prior art, is *prima facie* obvious to one of ordinary skill in the art. The addition or conversely, the subtraction, of optional components is done within the parameter of maintaining the composition on the substrate, i.e. Krzysik's tissue, as taught by Krzysik..

Therefore, for the reasons given above, it is the examiner's position that the instant claims are rendered prima facie obvious.

(F) Claims 14 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 to Krzysik et al in view of Mitchnick et al (6,103,267).

Appellant's arguments are similar to those made regarding the anticipation rejection. Appellant argues that Mitchnick does not cure Krzysik's deficiency in the disclosure of a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase.

Appellant's arguments are not persuasive for the following reasons:

The examiner has addressed the merits of WO 00/6409 above, which is incorporated herein. As discussed above, it is the examiner's position that WO 00/64409 is not deficient in the required limitations of the independent claims. WO 00/64409 is only deficient in the teaching of the instant dispersing agent. Therefore, Mitchnick is not relied upon to teach a composition with no more than 50% of components liquid at room temperature and no more than 50% of components solid at room temperature and a composition wherein 85% of the components form a single phase since Krzysik is not deficient in this sense. Mitchnick teaches the functional equivalency of Krzysik's dispersing agents and the instant dispersing agents. Absent evidence of unobviousness (which appellant has not demonstrated) of the instant dispersing agent versus the prior art's, it is prima facie obvious to substitute a conventional and known functionally equivalent dispersing agent with another conventional dispersing agent. MPEP 2144.06 states, In order to rely on equivalence as a rationale supporting an obviousness rejection, the

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equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958). In instant case, Mitchnick establishes this functional equivalency. Appellant has not addressed the examiner's motivation.

The examiner respectfully submits that the substitution of one dispersing agent would not depart from the from the claimed limitation in the independent claims.

Furthermore, the manipulation of such factors within the guidelines provided by the prior art, is prima facie obvious to one of ordinary skill in the art. The substitution of equivalent components is done within the parameter of maintaining the composition on the substrate, i.e. Krzysik's tissue.

Therefore, for the reasons given above, it is the examiner's position that the instant claims are rendered prima facie obvious.

(G) Claims 1-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30, 32-60 of copending Application No. 10/659969 and claims 1-59 of 10/659862.

Appellant argues that the double patenting rejections are premature and directs the examiner's attention to MPEP §804. Appellant states "Appellant would like to delay responding to this rejection."

Appellant's arguments are not persuasive for the following reasons: Firstly, it is noted that appellant has not argued the merits of the obviousness-type double patenting per se. It is the examiner's position that the instant applicant and co-pending applications are obvious variants of each other for the reasons set forth in the Grounds of Rejection section. Further, since it is the

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examiner's position that the claims are not in condition for allowance and the provisional rejections are not the only remaining rejections of record, the rejection is maintained.

(H) Claims 1-10, 12-13, 25-32, 34-41, 43, 52-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-33 US 5,869,075.

Appellant argues that US '075 does not claim a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Lastly, appellant argues that the disclosure of the patent may not be used to make the rejection.

Appellant's arguments are not persuasive for the following reasons:

Claim 1 is directed to a moisturizing and lubricating composition **comprising**:

- (a) from about 1% to about 40% of an emollient,
- (b) from about 1% to about 20% of a humectant,
- (c) from about 30% to about 90% of an immobilizing agent, and
- (d) from about 1% to about 40% of a compatibilizing agent,

wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

US '075 claims:

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A softening composition comprising:
from about 30 to about 90 weight percent hydrophilic solvent,
from about 10 to about 50 weight percent high molecular weight polyethylene glycol
having a molecular weight of about 720 or greater,
and from about 5 to about 40 weight percent of a C14 to C30 fatty alcohol,
said composition having a melting point from about 30°C. to about 70°C and a
penetration hardness of from about 5 millimeters to about 360 millimeters from about 30 to
about 90 weight percent hydrophilic solvent.

Dependent claim 23 claims:

The composition of claim 16 comprising:

- (a) about 10 weight percent cetyl alcohol (emollient-melting point of 56°C),
- (b) **about** 25 weight percent hydrogenated starch hydrolysate (humectant),
- (c) about 50 weight percent high molecular weight polyethylene glycol (immobilizing agent); and
- (d) about 15 weight percent propylene glycol (compatibilizing agent- melting point of -59°C).

All the components are in a melted form at a temperature of from about 45°C to about 80°C and thus form a single phase. About 35% of the components (propylene glycol and starch hydrolysate) are liquid at room temperature. About 60% of the components are solid at room temperature.

The examiner respectfully points out that the fact that US '075 has not explicitly claimed these properties does not differentiate the subject matter claimed since these properties are

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inherent. Therefore, it is the examiner's position that US '075 claims similar subject matter as claimed in the instant application.

Lastly, appellant argues that the disclosure of the patent may not be used to make the rejection. The examiner acknowledges that the disclosure of a US patent may not be used to reject the claims under double patenting unless the examiner is relying on the disclosure to define a term. However, in instant case the examiner has not relied on the disclosure and the argument is moot.

(I) Claims 1, 4-10, 13, 1517, 21-22, 25, 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of US 6475197.

Appellant argues that US '197 does not claim a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature.

Appellant's arguments are not persuasive for the following reasons:

Claim 1 is directed to a moisturizing and lubricating composition **comprising:**

- (a) from about 1% to about 40% of an emollient,
- (b) from about 1% to about 20% of a humectant,
- (c) from about 30% to about 90% of an immobilizing agent, and
- (d) from about 1% to about 40% of a compatibilizing agent,

wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and at least about 85%

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(by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

US '197 claims:

A body facing material having an outer surface, wherein said outer surface of said body facing material has a composition that enhances skin barrier consisting of:

(a) from about 0.1 to about 30 weight percent of natural fats or oils (emollient),

(b) from about 0.5 to about 10 weight percent of humectant,

(c) from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater (immobilizing agent) and from about 1 to about 30 weight percent of a C14 to C30 or greater fatty alcohol,

(d) from about 10 to about 90 weight percent hydrophilic solvent (compatibilizing agent),

(e) from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7 (dispersing agent);

(f) from about 0.1 to about 10 weight percent of sterol or sterol derivative (reads on instant sterols claimed);

The examiner respectfully points out that it is within the skill of an artisan to manipulate the amount to yield the instant claimed composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature. For instance, US '197 claims 5% as the lower limit of the hydrophilic solvent which is liquid at room temperature; 95% as the maximum limit of the high molecular weight PEG which is solid at room temperature (note applicant claims "about 90%" and applicant has not defined "about" to mean exactly in the specification, note MPEP 2111.01 IV);

Art Unit: 1616

10% as the maximum weight of the humectant, which is liquid at room temperature; and 1% as the lower limit of the fatty alcohols, which are solid at room temperatures. Clearly the maximum and minimum ranges claimed in US '197 yield a composition wherein no more than about 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature.

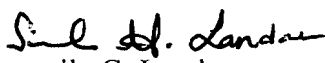
Therefore, it is the examiner's position that US '075 and the instant application are obvious variants of each other.

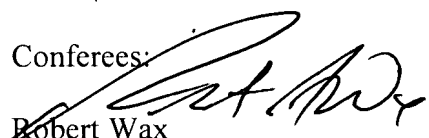
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

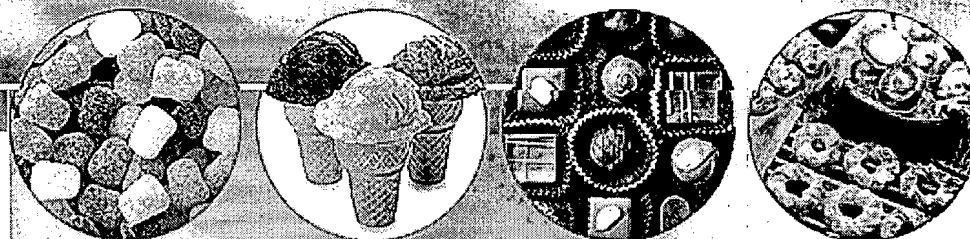

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Primary Examiner

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Starch Hydrolysates

Hydrogenated starch hydrolysates are a family of pleasant tasting bulk sweeteners used in a variety of products. They are exceptionally well suited for sugar-free candies because they do not crystallize. They blend well with flavors and are synergistic with low-calorie sweeteners.

Hydrogenated starch hydrolysates (HSH), including hydrogenated glucose syrups, maltitol syrups, and sorbitol syrups, are a family of products found in a wide variety of foods. They serve a number of functional roles, including use as bulk sweeteners, viscosity or bodying agents, humectants, crystallization modifiers, cryoprotectants and rehydration aids. They also can serve as sugar-free carriers for flavors, colors and enzymes. HSH were developed by a Swedish company in the 1960's and have been used by the food industry for many years, especially in confectionery products.

HSH are produced by the partial hydrolysis of corn, wheat or potato starch and subsequent hydrogenation of the hydrolysate at high temperature under pressure. The end product is an ingredient composed of sorbitol, maltitol and higher hydrogenated saccharides (maltitriitol and others). By varying the conditions and extent of hydrolysis, the relative occurrence of various mono-, di-, oligo- and polymeric hydrogenated saccharides in the resulting product can be obtained. A wide range of polyols (also known as sugar alcohols) that can satisfy varied requirements with respect to different levels of sweetness, viscosity and humectancy can, therefore, be produced.

The term "hydrogenated starch hydrolysate" can correctly be applied to any polyol produced by the hydrogenation of the saccharide products of starch hydrolysis. In practice, however, certain polyols such as sorbitol, mannitol and maltitol are referred to by their common chemical names. "Hydrogenated starch hydrolysate" is more commonly used to describe the broad group of polyols that contain

substantial quantities of hydrogenated oligo- and polysaccharides in addition to any monomeric or dimeric polyols (sorbitol/mannitol or maltitol, respectively).

The broad term HSH does not differentiate polyols having, for example, different levels of sweetness nor does it identify the principle polyol in the HSH. Common names for major HSH subgroups have, therefore, been developed. These common names are generally based on the most prevalent polyol comprising the HSH. For example, polyols containing sorbitol as the majority (50 percent or more) component are called sorbitol syrups; those with maltitol as the majority component are called maltitol syrups, maltitol solutions or hydrogenated glucose syrups. Polyols that do not contain a specific polyol as the majority component continue to be referred to by the general term "hydrogenated starch hydrolysate."

In the United States, HSH are provided by three manufacturers, SPI Polyols, Roquette America, Inc. and Archer Daniels Midland Company (ADM). Product examples of maltitol syrups include SPI Polyols' Maltisweet™ 3145 which is approximately 65 percent maltitol and Hystar® 5875 which is 60 percent maltitol and Roquette's Lycasin® 80/55 which is 55 percent maltitol. Sorbitol syrups include Roquette's 70/100 which is 75 percent sorbitol, SPI Polyols' Sorbo 70% and A-625 which contain 70 percent sorbitol and ADM's sorbitol syrup, called Sorbitol Solution, Noncrystallizing, NF, which is 70 percent sorbitol. Examples of products called by the general term HSH include Roquette's 75/400 and SPI Polyols' Hystar® 33/75. SPI Polyols also markets Liquid HSH (Stabilite®) and a powdered HSH (Stabilite® SD) through its joint venture with Grain Processing Corporation, Innova.

HSH-2093

HSH are outstanding humectants which do not crystallize, enabling the production of sugar-free confections with the same cooking and handling systems used to produce sugar candies. These products are used extensively in confections, baked goods, a broad range of other foods, dentifrices and mouthwashes.

HSH are nutritive sweeteners that provide 40 to 90 percent of the sweetness of sugar. Being polyols, HSH are not sugars and are used to provide sweetness, texture and bulk to a variety of sugarless products. Unlike sugars, HSH are not readily fermented by oral bacteria and are used to formulate sugarless products that do not promote dental caries.

HSH are also more slowly absorbed in the digestive tract. A portion of

HSH may be enzymatically hydrolyzed in the body to sorbitol, maltitol and glucose, however, this process is slow. Therefore, HSH have a reduced glycemic potential relative to glucose for individuals with and without diabetes. Since HSH are more slowly absorbed, a portion of HSH in a food reaches the lower digestive tract where it is metabolized by naturally occurring colonic bacteria. This results in a reduction in the available calories and permits its use as a reduced calorie alternative to sugar.

Generally Recognized as Safe (GRAS) affirmation petitions for HSH have been accepted for filing by the Food and Drug Administration. This allows manufacturers to produce and sell foods containing these sweeteners in the United States.

Hydrogenated Starch Hydrolysates

- Hydrogenated Starch Hydrolysates
- Pleasant tasting bulk sweeteners that blend well with other sweeteners and are synergistic with low-calorie sweeteners (e.g., acesulfame K, aspartame, neotame, saccharin and sucralose)
- Blend well with flavors and can mask unpleasant off-flavors
- Reduced calorie alternatives to sugar, having not more than 3 calories per gram
- Used in a variety of products; exceptionally well suited for sugar-free candies because they do not crystallize
- Do not contribute to the formation of dental caries
- May be useful as alternatives to sugar for people with diabetes on the advice of their physician

Does Not Promote Tooth Decay

Polyols, including HSH, are resistant to metabolism by oral bacteria that break down sugars and starches to release acids that may lead to cavities or erode tooth enamel. They are, therefore, non-cariogenic. The usefulness of polyols as alternatives to sugars and as a part of a comprehensive program including proper dental hygiene has been recognized by the American Dental Association.

Use in the Diet of People with Diabetes

Control of blood glucose, lipids and weight are the three major goals in diabetes management today. HSH absorption is slow and incomplete. Therefore, the rise in blood glucose and insulin response associated with the ingestion of glucose is significantly reduced when HSH are used as alternative sweeteners. The reduced caloric value (75 percent, or less, that of sugar) of HSH is consistent with the objective of weight control. Products in which HSH replace sugar may, therefore, be of use providing a wider variety of reduced calorie and sugar-free choices to people with diabetes.

Recognizing that diabetes is complex and requirements for its management may vary between individuals, the usefulness of HSH should be discussed between individuals and their physicians. Foods sweetened with HSH products may contain other ingredients that also contribute calories and other nutrients. These must be considered in meal planning.

Reduced-Calorie Alternatives to Sugar

Absorption of HSH by the body is slow, allowing a portion of HSH to reach the large intestine where metabolism yields fewer calories. Therefore, unlike sugar that contributes 4 calories per gram, the caloric contribution of HSH is not more than 3 calories per gram. For a product to qualify as "reduced calorie" in the United States, it must have at least a 25 percent reduction in calories. HSH may, therefore, be of use in formulating reduced calorie food products.

The lower caloric value of HSH and other polyols is recognized in other countries. For example, the European Union has provided a Nutritional Labeling Directive stating that all polyols, including HSH, have a caloric value of 2.4 calories per gram.

Safety

The safety of HSH products and their components is substantiated by a broad range of safety studies in man and animals, including long term feeding, multigeneration reproduction and teratology studies.

The Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) has reviewed the safety information and concluded that maltitol syrups are safe. JECFA established an acceptable daily intake (ADI) for "maltitol syrup" of "not specified," meaning no limits are placed on its use. An ADI of "not specified" is the safest category in which JECFA can place a food ingredient. JECFA's decisions are often adopted by many small countries that do not have their own agencies to review food additive safety. In 1984, the Scientific Committee for Food of the

European Union evaluated maltitol syrups and concluded it was not necessary to set an ADI for maltitol syrups.

In the United States, Generally Recognized as Safe (GRAS) petitions for HSH products have been accepted for filing. Once a GRAS affirmation petition has been accepted for filing, food manufacturers may use the ingredient. Products from the HSH family are approved in many other countries, including Canada, Japan and Australia.

Multiple Ingredient Approach to Calorie Control

HSH, although less sweet than sucrose, blend well with other sweeteners and flavors and can mask unpleasant off-flavors such as bitter notes. HSH products are synergistic with low-calorie sweeteners. Applications for HSH include confectioneries, baked goods, icings and frozen desserts. In baked goods, for example, HSH products not only offer sweetness but also moisture control, texture improvement, crystallization inhibition, less browning (allowing less chance of burning), stability improvement with extended shelf life and flavor improvement.

Future

Health conscious Americans continue to demand additional good-tasting products with less calories and fat. A wide variety of low-calorie and reduced-calorie ingredients can provide products with improved taste and texture, increased stability and more choices for the consumer. The availability of various low-calorie and reduced-calorie ingredients allows food manufacturers to choose the most appropriate ingredient, or combination of ingredients, for a given product. Recent research shows that more than 100 million Americans consume low-calorie products. Over half of these consumers would like additional low-calorie products to be available. The primary interest is in desserts and sweets, including baked goods, candy, chocolates and ice cream. HSH can be helpful in making many of these products possible.

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Dimethicone Copolyol Complex of natural silica, acts as a spreading agent for easy application of product; also functions as a moisturizer.
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Dimethicone Copolyol

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 Conditioning and thickening agent.
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E-Ma

Polydimethylsiloxane

From Wikipedia, the free encyclopedia
(Redirected from Dimethicone)

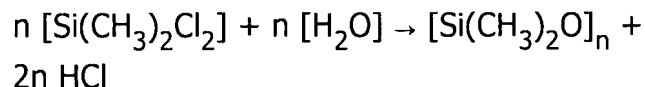
Polydimethylsiloxane (PDMS) is the most widely used silicon-based organic polymer, and is particularly known for its unusual rheological (or flow) properties. It is optically clear, and is generally considered to be inert, non-toxic and non-flammable. PDMS has been assigned CAS number 63148-62-9, and is occasionally called **dimethicone**. It is one of several types of silicone oil (polymerized siloxane).

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- 1 Chemistry
- 2 Mechanical properties
- 3 Chemical compatibility
- 4 Applications
- 5 See also
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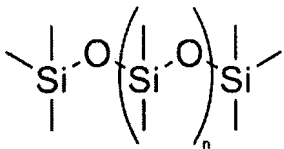
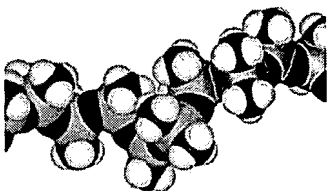
Chemistry

The chemical formula for PDMS is $(\text{H}_3\text{C})_3[\text{Si}(\text{CH}_3)_2\text{O}]_n\text{Si}(\text{CH}_3)_3$, where *n* is the number of repeating monomer $[\text{SiO}(\text{CH}_3)_2]$ units. Industrial synthesis can begin from dimethylchlorosilane and water by the following net reaction:



During polymerization, this reaction evolves potentially hazardous hydrogen chloride gas. For medical uses, a process was developed where the chlorine atoms in the silane precursor were replaced with acetate groups, so that the reaction product of the final curing process is nontoxic acetic acid (vinegar). As a side effect, the curing process is also much slower in this case. This is the chemistry used in consumer applications, such as silicone caulk and adhesives.

Silane precursors with more acid-forming groups and fewer methyl groups, such as

Polydimethylsiloxane	
	
	
IUPAC name	poly(dimethylsiloxane)
Other names	PDMS dimethicone E900
Identifiers	
CAS number	63148-62-9 (http://www.emolecules.com/cgi-bin/search?t=ss&q=63148-62-9&c=0&v=)
Properties	
Molecular formula	$(\text{C}_2\text{H}_6\text{OSi})_n$
Density	965 kg m ^{−3}
Melting point	N/A (vitrifies)
Boiling point	below about 200 °C
Except where noted otherwise, data are given for materials in their standard state (at 25 °C, 100 kPa) Infobox disclaimer and references	

Glycerol

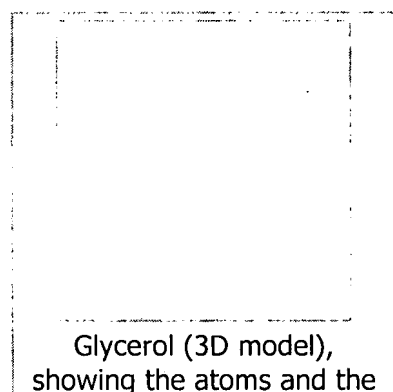
From Wikipedia, the free encyclopedia

Glycerol is a chemical compound with the formula HOCH₂CH(OH)CH₂OH. This colorless, odorless, viscous liquid is widely used in pharmaceutical formulations. Also commonly called **glycerin** or **glycerine**, it is a sugar alcohol, and is sweet-tasting and of low toxicity. Glycerol has three hydrophilic alcoholic hydroxyl groups that are responsible for its solubility in water and its hygroscopic nature. Its surface tension is 64.00 mN/m at 20 °C , and it has a temperature coefficient of -0.0598 mN/(m K). It is a central component of lipids.

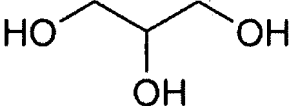
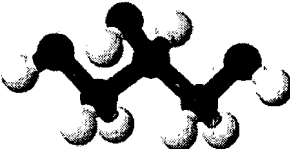
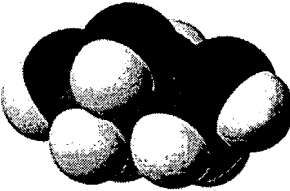
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 - 2.3 Potential uses
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- 5 See also
- 6 References
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Synthesis



Until recently, synthetic glycerol was mainly manufactured at an industrial scale from

Glycerol	
	
	
	
IUPAC name	Propane-1,2,3-triol
Other names	glycerin glycerine propane-1,2,3-triol 1,2,3-propanetriol 1,2,3-trihydroxypropane glyceritol glycyl alcohol
Identifiers	
CAS number	56-81-5 (http://www.emolecules.com/cgi-bin/search?t=ss&q=56-81-5&c=0&v=)
SMILES	OCC(O)CO
Properties	
Molecular formula	C ₃ H ₅ (OH) ₃
Molar mass	92.09382 g/mol
Structure and Density	1,261 g/cm ³
Melting point	18 °C (64 °F)
Boiling point	290 °C (554 °F)
Spectral data	IR, ¹ H NMR, MS
Viscosity	1.5 Pa·s
MSDS	Infobox External references
Flash point	160 °C (closed cup)

emulsion stabilizer, emollient, moisturizer and viscosity builder in creams and lotions. It is also used as an opacifying and pearling agent in cosmetics. Glycerol stearate can be of plant origin (corn-based), animal source or synthetic and is considered to be biodegradable, practically non-toxic orally and causes no skin and minimal eye irritation. It is dispersible in water and is also soluble in oil and alcohol, making it an ideal ingredient for cosmetics. Glycerol monostearate (GMS) is also used as an ingredient in cosmetics as well as in food products. In a clinical trial with over 1,200 patients with eczema, glycerol monostearate was found to produce absolutely no adverse reactions in a test of common emulsifiers (all other emulsifiers tested did cause adverse reactions in a significant percentage of patients). It is used to keep bakery goods fresh, improve flour quality, and as an emulsifying and whipping agent for ready-to-eat products. It is also used in ice cream formulations, starch products, milk products, chewing gum, chocolates and other foods. It also serves as a softer in textiles and as an external lubricant for plastics. Another form of this chemical often used in cosmetics is glycerol monohydroxystearate, an off-white wax with physical properties similar to beeswax. It provides the functional characteristics of glycerol stearate and enhanced properties such as improved emulsion stability, bodying and thickening properties and greater dispersability of colorants and active materials. Semi-synthetic forms of glycerol stearate often use stearic acid isolated from palm oil as a starting material, another waxy fatty acid widely used in cosmetics and soap. The glycerol component of glycerol stearate can be from beef fat, petroleum, or vegetable source and is itself used as a solvent and humectant (maintains the desired moisture level).

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Chemistry:

Glycerol stearate is a fatty compound ($C_{17}H_{35}COO)_3C_3H_5$). The formula for the hydrocarbon radical (R) in the fat glycerol stearate is $C_{17}H_{35}$. Glycerol stearate has a melting point of $58^{\circ}C$ / $136^{\circ}F$, an acid value



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Melting points of some common oils can be taken from the table below:

Oil	Melting Temperature (°C)
Castor Oil	-18
Coconut Oil	25
Cotton Seed Oil	-1
Linseed Oil	-24
Mutton Tallow	42
Olive Oil	-6
Palm Kernel Oil	24
Palm Oil	35
Peanut Oil	3
Rapeseed Oil	-10
Sunflower Oil	-17
Soybean Oil	-16
Tung Oil	-2.5

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°C

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Length

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In this study, the batch production of particles from PEG with a weight average molecular weight (M_w) of 6000 and 10000 has been reported. The experimental results have been presented in terms of particle size, shape, morphology, and particle size distribution, which are dependent on the molecular weight, nozzle diameter, and process conditions. Moreover, a flow and a solidification model have been applied to study the effect of the rate of nucleation on the particle size distribution and the effect of different parameters on the particle shape, respectively.

4.2. Experimental

4.2.1. Materials

Poly(ethylene glycol) (PEG) having a weight average molecular weight (M_w) of 6000 and 10000 were purchased from Aldrich, The Netherlands. Digital scanning calorimetric (DSC) measurements were carried out to determine the melting points (T_m) and the heat of melting (ΔH_m) of PEG 6000 and 10000. The crystallinity of the PEG calculated using ΔH_m of 100 % crystalline PEG (196.8 J/g [7]) are provided in Table 4.1. High purity CO₂, 99.99 %, was used in the experiments. The materials were used without any further purification.

Table 4.1. The physical properties of PEG of different weight average molecular weights (M_w)

M_w	T_m (K)	ΔH_m (J/g)	Crystallinity %
6000	332	185.1	94
10000	338	181.4	92

4.2.2. Apparatus

The batch set up is shown schematically in Fig. 4.1. The set up, designed and constructed, in our laboratory can withstand a pressure of 25 MPa at 473 K. A cylinder (150 ml), tubes, nozzle and valves were obtained from Swagelok, The Netherlands. In the set up, a pressure sensor (Dynisco, USA) is mounted in the CO₂ line using a connector just before to the entrance of the cylinder. Before the nozzle, a ball valve (open-close) is used as it can be opened or closed more quickly. The cylinder and the tubes are heated using a heating element, whose temperature is controlled using a Eurotherm controller, The Netherlands. The set up is mounted on the supports, which oscillate, very slowly, over 180 ° in order to achieve better mixing. Additionally, an insert having left-right elements in the cylinder also improves the mixing. CO₂ is added using a membrane pump (Lewa, USA) and heated in a double pipe heat exchanger prior to its addition. A

PEG-10,000
64.8 °C

↓
64.8 °C

Gas Chromatographic Determination of Tocopherols and Sterols in Soya Sludges and Residues

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2010 East Hennepin Avenue, Minneapolis, Minnesota 55413

Abstract

A method is described for determining the individual and total sterols and tocopherols of soya sludges and residues. The method involves saponification of the sample followed by gas chromatographic analysis of the unsaponifiables. Data are presented on the reproducibility and accuracy of the method.

Introduction

SOYBEAN OIL is one of the sources of naturally occurring tocopherols and sterols. In the deodorization of this oil, a concentrate of the tocopherols and sterols is obtained which is called deodorizer distillate. A second type of concentrate is obtained when after hydrolysis of soybean acid soapstock, the fatty acids are distilled. The residue from the distillation is a good source of sterols.

In the past, it has been common to employ two separate analytical methods to determine the tocopherol and sterol content of soya sludges and residues. Total tocopherol was determined by the Emmerie-Engel method (5) and total sterol by the digitonide procedure (7). Neither of these methods is specific, that is, any compound which is oxidized by the reagent in the Emmerie-Engel method will be counted as tocopherol, and with the digitonide procedure for sterols, any compound that will precipitate with digitonin is counted as a sterol. Furthermore, these methods do not differentiate among the different types of sterols and tocopherols that usually are present.

In recent years publications have appeared describing the gas chromatography of sterols and tocopherols (2-4,6,8-11); however none of these apply specifically to the by-products from processing of soybean oil. This paper presents a gas chromatographic procedure for determining the individual, as well as the total tocopherols and sterols in soybean oil deodorizer distillate and distillation residues. The procedure involves the saponification of samples to free the tocopherols and sterols that are present as esters. The tocopherols and sterols then are extracted with diethyl ether and the extracts subsequently gas chromatographed.

Experimental Procedures

Reagents and Apparatus

Squalane Internal Standard Solution. Approximately 0.1 g (± 0.0001 g) of distilled squalane (Applied Science Laboratories, State College, Pa.) was weighed into a 100 ml volumetric flask and diluted to the mark with reagent grade chloroform.

Potassium Hydroxide Solution. Potassium hydroxide, 160 g, was dissolved in 100 ml of distilled water.

Pyrogallol Solution. Pyrogallol, 5 g, was dissolved in 95 ml of absolute ethyl alcohol. This solution was prepared fresh each day.

α -Tocopherol Standard. This compound was purchased from Distillation Products Ind., Rochester, N.Y.

Stigmasterol Standard. Stigmasterol isolated from soya sludge was purified by liquid column chromatography on Florisil. The purified product had a melting point of 169.5-170.5 C.

Gas Chromatograph Column Packing. Three hundred milliliters of a toluene solution containing 0.9 g of silicone gum rubber SE-30 (General Electric Co., Schenectady, N.Y.) was added to 26 g Gas Chrom Q (Applied Science Lab., State College, Pa.) in a one liter flask. The solvent was stripped off with a water aspirator while the mixture was stirred and heated in a water bath at 70 C. After the packing became free-flowing, it was transferred to a Petri dish and heated at 70 C on a hot plate until no solvent odor was detected.

Gas Chromatographic Column. The glass column was 6 ft long with an internal diameter of 3.5 mm and bent in the shape of a U. Prior to packing, the column was rinsed with potassium dichromate-sulfuric acid cleaning solution for 5 min. Then 500 ml of distilled water were flushed through the column, followed by 200 ml of absolute methyl alcohol. Then the column was rinsed with 1% dimethyl dichlorosilane in chloroform, washed with 100 ml absolute methyl alcohol and dried by aspirating with air. With the aid of a vibrator the column was filled by pouring approximately 6 in. of packing alternately into each leg until the packing level was 2 in. from the inlet end and $\frac{1}{2}$ in. from the outlet end. Finally, the ends of the column were plugged with glass wool. The glass wool had been rinsed previously with a 1% solution of dimethyl dichlorosilane in chloroform, washed with absolute methyl alcohol, and air dried.

The packed column was conditioned in the instrument first by flushing with helium for 5 min then, after turning off the helium flow, by heating at 245 C for 1 hr. At this time the helium flow was turned on and the instrument left at this temperature for 15 hr.

Gas Chromatograph. Analyses were performed on a Model 400 flame ionization gas chromatograph manufactured by Hewlett Packard, Avondale, Pa. The operating conditions of the chromatograph were: column temp. 225 C, injection port temperature 270 C, detector temperature 250 C, range 100, attenuation 16, hydrogen flow rate 50 cc/min, helium flow rate 150 cc/min, air flow rate 350 cc/min.

Approximately 0.2 g of sample was accurately (± 0.0001 g) weighed into a 50 ml round bottom flask. Then, 4 ml of a 5% solution of pyrogallol in absolute ethyl alcohol were added to prevent oxidation of the tocopherols during saponification. A water cooled condenser was attached to the flask and the solution was heated to reflux, at which time 1 ml of 60% aqueous potassium hydroxide was added. The solution was allowed to reflux 3 min and the flask was removed and cooled under tap water.

Distilled water, 20 ml, was added to the flask and the solution was transferred quantitatively to a 125 ml separatory funnel. Two 10 ml portions of diethyl ether were used to rinse the flask for quantitative transfer. The solution in the separatory funnel was extracted with the diethyl ether, taking care not to